

NOTICE OF INTENT

Department of Environmental Quality
Office of the Secretary
Legal Affairs Division

Miscellaneous Amendments for NRC Compatibility
(LAC 33:XV.102, 328, 713, and 763) (RP051ft)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Radiation Protection regulations, LAC 33:XV.102, 328, 713, and 763 (Log #RP051ft).

This rule is identical to federal regulations found in 10 CFR 32 & 35, which are applicable in Louisiana. For more information regarding the federal requirement, contact the Regulation Development Section at (225) 219-3985 or Box 4302, Baton Rouge, LA 70821-4302. No fiscal or economic impact will result from the rule. This rule will be promulgated in accordance with the procedures in R.S. 49:953(F)(3) and (4).

The changes in the state regulations are Category B & C (must do) requirements for the state of Louisiana to remain an NRC agreement state. The basis and rationale for this Rule are to be compatible with federal regulations and maintain an adequate Agreement State program. This rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required.

This rule has no known impact on family formation, stability, and autonomy as described in R.S. 49:972.

A public hearing will be held on June 24, 2010, at 1:30 p.m. in the Galvez Building, Oliver Pollock Conference Room, 602 N. Fifth Street, Baton Rouge, LA 70802. Interested persons are invited to attend and submit oral comments on the proposed amendments. Should individuals with a disability need an accommodation in order to participate, contact Donald Trahan at the address given below or at (225) 219-3985. Two hours of free parking are allowed in the Galvez Garage with a validated parking ticket.

All interested persons are invited to submit written comments on the proposed regulation. Persons commenting should reference this proposed regulation by RP051ft. Such comments must be received no later than July 1, 2010, at 4:30 p.m., and should be sent to Donald Trahan, Attorney Supervisor, Office of the Secretary, Legal Affairs Division, Box 4302, Baton Rouge, LA 70821-4302 or to FAX (225) 219-3398 or by e-mail to donald.trahan@la.gov. The comment period for this rule ends on the same date as the public hearing. Copies of this proposed regulation can be purchased by contacting the DEQ Public Records Center at (225) 219-3168. Check or money order is required in advance for each copy of RP051ft. This regulation is available on the Internet at www.deq.louisiana.gov/portal/tabid/1669/default.aspx.

This proposed regulation is available for inspection at the following DEQ office locations from 8 a.m. until 4:30 p.m.: 602 N. Fifth Street, Baton Rouge, LA 70802; 1823 Highway 546, West Monroe, LA 71292; State Office Building, 1525 Fairfield Avenue, Shreveport, LA 71101; 1301 Gadwall Street, Lake Charles, LA 70615; 111 New Center Drive, Lafayette, LA 70508; 110 Barataria Street, Lockport, LA 70374; 201 Evans Road, Bldg. 4, Suite 420, New Orleans, LA 70123.

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Executive Counsel

Title 33**ENVIRONMENTAL QUALITY****Part XV. Radiation Protection****Chapter 1. General Provisions****§102. Definitions and Abbreviations**

As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain chapter may be found in that chapter.

* * *

Authorized Nuclear Pharmacist—a pharmacist who ~~is~~:

1. is board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or
2. is identified as an authorized nuclear pharmacist on a department, licensing state, Nuclear Regulatory Commission, or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or
3. is identified as an authorized nuclear pharmacist on a permit issued by the department, licensing state, Nuclear Regulatory Commission, or agreement state specific licensee of broad scope authorized to permit the use of radioactive material in the practice of nuclear pharmacy; or
4. meets the requirements specified in LAC 33:XV.763.K and M.

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AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 19:1421

(November 1993), LR 20:650 (June 1994), LR 22:967 (October 1996), LR 24:2089 (November 1998), repromulgated LR 24:2242 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2563 (November 2000), LR 26:2767 (December 2000), LR 30:1171, 1188 (June 2004), amended by the Office of Environmental Assessment, LR 31:44 (January 2005), LR 31:1064 (May 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:811 (May 2006), LR 32:1853 (October 2006), LR 33:1016 (June 2007), LR 33:2175 (October 2007), LR 34:982 (June 2008), LR 36:**

Chapter 3. Licensing of Radioactive Material

Subchapter D. Specific Licenses

§328. Special Requirements for Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material

A. - J.2.b.i. ...

ii. this individual meets the requirements specified in LAC 33:XV.763.~~J.~~K.2 and M and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

J.2.b.iii. - K.2. ...

L. Licensing the Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use

1. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Chapter 7 for use as a calibration, transmission, or reference source or for the uses listed in LAC 33:XV.739, ~~and 741~~, and 747 of these regulations will be approved if the following conditions are met.

L.1.a. - M.4.g. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and

Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 24:2092 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2569 (November 2000), LR 26:2768 (December 2000), LR 27:1228 (August 2001), LR 30:1664 (August 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2526 (October 2005), LR 33:2179 (October 2007), LR 36:**

Chapter 7. Use of Radionuclides in the Healing Arts

§713. Suppliers

A. A licensee shall use for medical use only:

1. ...

2. reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration; ~~and~~

3. sealed sources or devices non-commercially transferred from a Nuclear Regulatory Commission Medical Licensee, a licensing state medical use licensee, or an agreement state medical use licensee; and

34. teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2103 (November 1998), LR 36:**

§763. Training

A. - E.4.iii. ...

F. Training for Use of Manual Brachytherapy Sources. Except as provided in Subsection B of this Section, the licensee shall require the authorized user of a manual brachytherapy source for the uses authorized in LAC 33:XV.741 to be a physician:

1. who is certified by a medical specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the requirements in Subparagraph F.2.~~d~~c of this Section. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

F.1.a. - 2.a.ii.(f).

b. has completed three years of supervised clinical experience in radiation oncology under the supervision of an authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in Subparagraph F.2.~~b~~a.ii of this Section; and

c. has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in Subparagraph F.1.a, or Paragraph F.2.a and ~~Subparagraph F.2.c~~b of this Section, and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized in LAC 33:XV.741.

G. - I.2.a.ii.(f). ...

b. has completed three years of supervised clinical experience in radiation therapy under the supervision of an authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation

Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in Subparagraph ~~I.2.b~~ I.2.a.ii of this Section; and

c. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraph I.1.a or ~~Paragraph I.2 and Subparagraph I.2.c, I.2.a and b~~ and Paragraph I.3 of this Section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in this Subsection or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

I.3 - M. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:1186 (June 2004), amended by the Office of Environmental Assessment, LR 31:1061 (May 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:814 (May 2006), LR 34:983 (June 2008), LR 34:2121 (October 2008), LR 36:**